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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/871,125	05/31/2001	Michael W. Pariza	960296.97958	2562

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EXAMINER

HUI, SAN MING R

ART UNIT	PAPER NUMBER
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1617

DATE MAILED: 01/13/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application N .	Applicant(s)	
	09/871,125	PARIZA ET AL.	
	Examiner	Art Unit	
	San-ming Hui	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 September 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14, 17-19 and 48-53 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4, 10-14, 17-19 and 48 is/are rejected.
- 7) ☒ Claim(s) 5-9 and 49-53 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicant's response filed September 13, 2004 have been entered.

Claims 1-14, 17-19, and 48-53 are pending.

Claim 53 should not be withdrawn from consideration since it is depending from claim 9.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 2, 4, 10-14, and 17-19 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the lipoxxygenase inhibitors listed in claims 3 and 9, does not reasonably provide enablement for other suitable lipoxxygenase inhibitors. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. In the instant case, the specification fails to provide information that would allow the skilled artisan to practice the instant invention without undue experimentation. Attention is directed to *In re Wands*, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:

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- 1) the quantity of experimentation necessary,
- 2) the amount of direction or guidance provided,
- 3) the presence of absence of working examples,
- 4) the nature of the invention,
- 5) the state of the prior art,
- 6) the relative skill of those in the art
- 7) the predictability of the art, and
- 8) the breadth of the claims.

Applicant fails to set forth the criteria that define a "lipoxygenase inhibitor".

Additionally, Applicant fails to provide information allowing the skilled artisan to ascertain these compounds without undue experimentation. In the instant case, only a limited number of "lipoxygenase inhibitor" examples are set forth, thereby failing to provide sufficient working examples. It is noted that these examples are neither exhaustive, nor define the class of compounds required. Please note that there are no common structural similarities among the compounds recited. The only common property of these compounds is their ability to inhibit lipoxygenase. It is not known to what degree of inhibition a lipoxygenase inhibitor compound has in order to be useful in the instant invention. The pharmaceutical art requires each embodiment to be individually assessed for physiological activity. The instant claims read on all "lipoxygenase inhibitor(s)", necessitating an exhaustive search for the embodiments suitable to practice the claimed invention. Applicants fail to provide information sufficient to practice the claimed invention, absent undue experimentation.

Response to arguments

Applicant's arguments filed September 13, 2004 averring the skilled artisan being able to familiar with newly identified lipoxygenase inhibitors since the instant specification listed 26 examples of lipoxygenase inhibitors have been considered, but are not found persuasive. Examiner notes that the 26 examples disclosed in the instant specification have not had any common core structure that would lead to one of skilled in the art to determine whether a particular compound would be a lipoxygenase or not. There is no structural-activities relationship disclosed in the specification as to what structure or moieties or functional group would make the compounds as useful to inhibit lipoxygenase. Without such information and guidance, one of skilled in the art will be required to perform undue experimentation to ascertain all lipoxygenase inhibitors encompassed by the claims in order to practice the full scope of the claims.

Furthermore, applicant essentially define the instant subject matter by using functional language at point of novelty. Attention is directed to *General Electric Company v. Wabash Appliance Corporation et al* 37 USPQ 466 (US 1938), at 469, speaking to functional language at the point of novelty as herein employed: "the vice of a functional claim exists not only when a claims is "wholly" functional, if that is ever true, but when the inventor is painstaking when he recites what has already been seen, and then uses conveniently functional language at the exact point of novelty". Functional language at the point of novelty, as herein employed by Applicants, is further admonished in *University of California v. Eli Lilly and Co.* 43 USPQ2d 1398 (CAFC 1997) at 1406:

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stating this usage does “little more than outlin[e] goals appellants hope the recited invention achieves and the problems the invention will hopefully ameliorate”.

Applicants functional language at the point of novelty fails to meet the requirements set forth under 35 USC 112, first paragraph. Claims employing functional language at the point of novelty, such as Applicants’, neither provide those elements required to practice the inventions, nor “inform the public during the life of the patent of the limits of the monopoly asserted” *General Electric Company v. Wabash Appliance Corporation et supra*, at 468. Claims thus constructed provide no guidance as to medicaments employed, levels for providing therapeutic benefit, or provide notice for those practicing in the art, limits of protection. Simply stated, the presented claims are an invitation to experiment, not reciting a specific medicament regimen useful for practicing the instant invention.

Applicant’s arguments filed September 13, 2004 averring one or more examples deems adequate support for the use of the inhibitor in general by citing *In re Herschler* and *University of Rochester v. G.D. Searle*, have been fully considered, but are not found persuasive. Firstly, *In re Herschler* was discussed in *University of Rochester v. G.D. Searle* that “Although cases such as *Unocal*, *Enzo*, *Edwards*, and *Herschler* demonstrate that patent applicants have some flexibility in the “mode selected for compliance” with the written description requirement, neither those cases nor any other cases cited by *Rochester* eliminate the requirement that the patent specification set forth enough detail to allow a person of ordinary skill in the art to understand what is claimed and to recognize that the inventor invented what is claimed”. In other words,

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the instant specification must have adequate description to enable one of skilled in the art to practice the claimed invention. In the instant case, such description is not found in the instant specification. The heart of the issue is not how many examples are disclosed. The question is "does the instant specification disclose sufficient information to one of skilled in the art so that one can practice the full scope of the invention?". As discussed above, since the claim language herein recited is so functional, it merely outline what the applicant hoping to accomplish by employing compounds that will perform certain function, i.e., inhibit lipoxxygenase, without reciting what these compounds are. One of skilled in the art would be required undue experimentation to ascertain all of the compounds encompassed by the claims. Thus, the presented claims are an invitation to experiment, not reciting a specific medicament regimen useful for practicing the instant invention.

Applicant's arguments filed September 13, 2004 averring other patents reciting the board terms "lipoxxygenase inhibitors" have been considered, but are not found persuasive. Examiner notes that U.S. patent is merely properties, not legal precedence.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 3 and 48 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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Claims 3 and 48 contain the trademark/trade name "BHA" and "BHT". Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the trademark/trade name is used to identify/describe lipxygenase inhibitors and, accordingly, the identification/description is indefinite.

Response to arguments

Applicant's arguments filed September 13, 2004 averring the terms "BHA" and "BHT" as commonly known have been considered, but are not found persuasive. Examiner notes that "BHA" and "BHT" can mean butylated hydroxyanisole and butylated hydroxytoluene respectively. However, they can also mean, for example, bromo-hexanoic acid and bromo-hexyl thiazole. The problem is that the instant specification does not clearly define what these two agents are. Merely giving the acronyms of the herein recited compounds is insufficient for defining the herein claimed invention.

Allowable Subject Matter

Claims 5-9 and 49-53 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to San-ming Hui whose telephone number is (571) 272-0626. The examiner can normally be reached on Mon 9:00 to 1:00, Tu - Fri from 9:00 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, PhD., can be reached on (571) 272-0629. The fax

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phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


San-ming Hui
Primary Examiner
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